Valvuloplasty Balloon Catheter Assisted Compliant Aortic Annulus Sizing with Variable Elliptical Ratio

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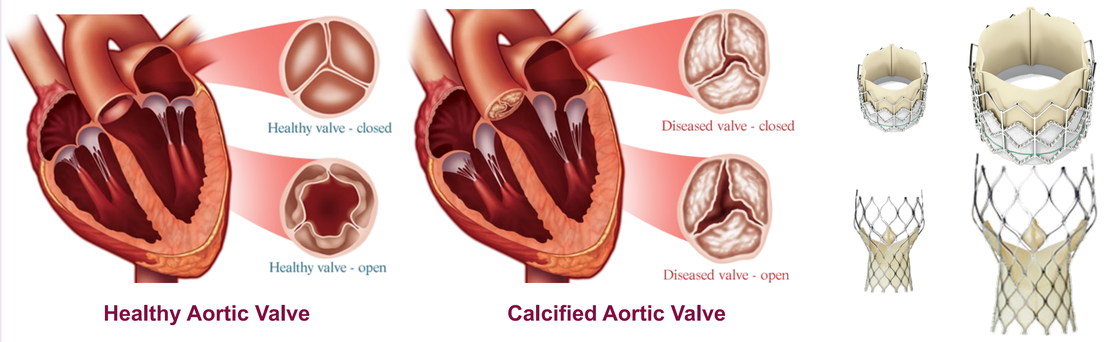
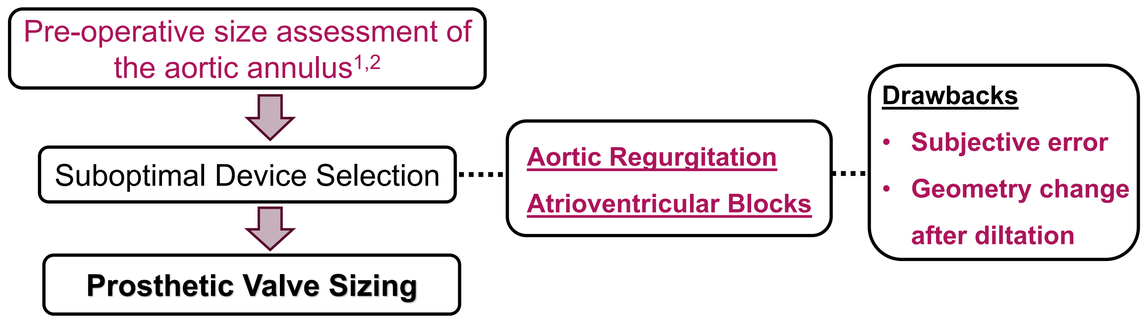
Statement of clinical need

- **Aortic Stenosis** (AS) is a serious heart disease characterized by a narrowing of the aortic valve opening.
- **Transcatheter aortic valve implantation** (TAVI) is a minimally invasive surgery for stent-valve replacing the function of a diseased native valve.



Healthy and calcified aortic valve closure; Balloon-expandable valve and Self-expandable valve



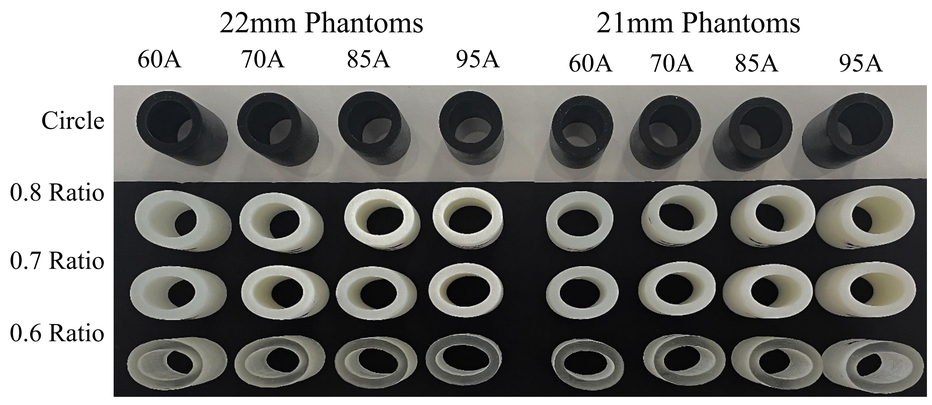
Aim of this work

We proposed an intra-operative method for determining the aortic annular diameter based on its compliance and elliptical geometry properties from a robotized aortic valvuloplasty balloon catheter.

Methodology

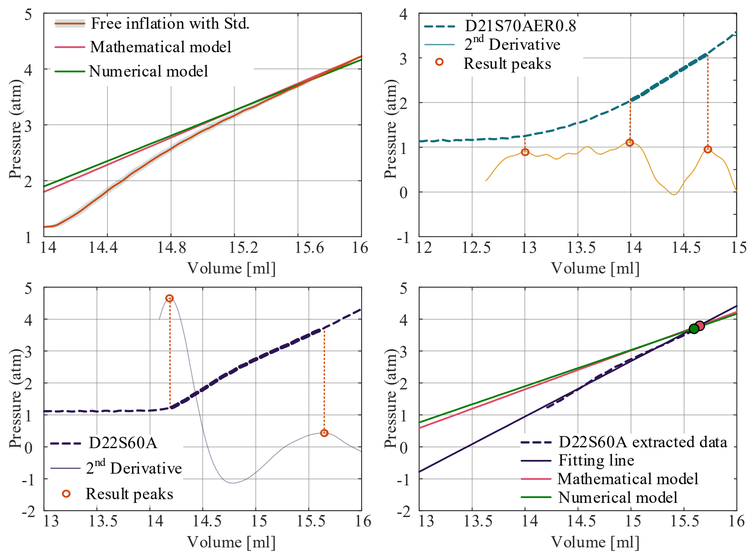
The Idealised Annular Phantoms

- The implantation region was approximated as a compliant cylinder;
- The cylinders were obtained by 3D printing with Tango Black Plus, VeroClear, and Agilus 30;
- Two different diameters (21,22mm);
- Four different shore hardness (60A, 70A, 85A, and 95A);
- One circular and three elliptical ratios (0.6, 0.7, and 0.8);
- 40 mm length with 5 mm thickness.



Experimental Protocol

- The cylindrical part of the balloon was placed inside the phantom.
- The balloon was inflated until the internal pressure increased above its nominal pressure (4.5 atm);
- Constant flow rate = 1 ml/s;
- 5 tests for each phantom configuration were performed;

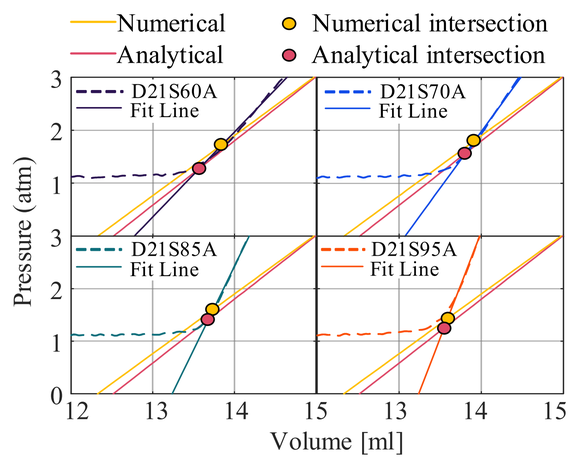


Sizing Algorithm

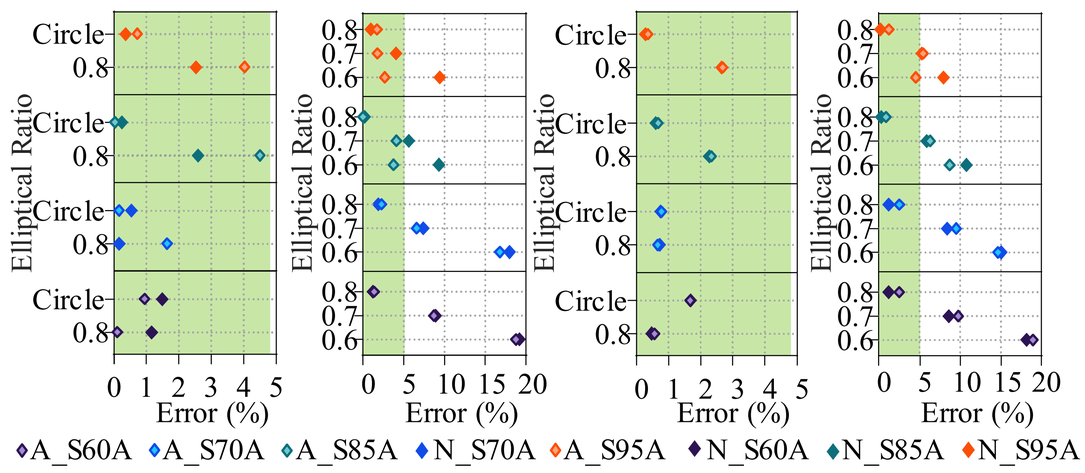
❖The sizing algorithm relies on the analytical model or numerical model and a differential peak selection method to identify, within the acquired dataset, the point of deviation from the free inflation;

❖Peak selection method for elliptical short diameter estimation and the intersection between fitted p-v data and the free inflation model for circular diameter estimation.

Results and Discussion



- **Intersection point** for calculating the estimated circular annular phantom.
- The numerical results are larger than the analytical results.



- The proposed sizing algorithm has excellent accuracy for circular idealized compliant annular diameter estimation (maximum error 1.69%).
- The assessment of the short diameter of the stiffer elliptical annular, such as those with shore hardness 85A and 95A, shows good accuracy and reproducibility via an analytical model.
- When the elliptical annulus has a ratio of 0.8, its equivalent diameter can be evaluated as the circular diameter (21 and 22 mm of the same circumference, resulting in low error.

Conclusion

In this work, the possibility of sizing the aortic annulus from intra-balloon pressure and volume data, acquired from a balloon catheter, was investigated:

- A robotized inflation device capable of controlling balloon inflation and constantly acquiring intra-balloon pressure and volume data was developed;
- The inflation device was interfaced with a commercial balloon catheter and experiments in simplified aortic annular phantoms were performed;
- The performance of the algorithm was assessed on experimental data obtained from tests on phantoms. In cases of circular and 0.8 elliptical ratio phantoms, the algorithm exhibited high precision and great repeatability.
- The estimation results of the short diameter for the elliptical annulus show an acceptable error when the stiffness of the tissue is around shore hardness 85A and 95A.

[1] [Möllmann et al., Complications of transcatheter aortic valve implantation (TAVI): how to avoid and treat them, 2015]
[2] [Figulla et al., The transcatheter valve technology pipeline for treatment of adult valvular heart disease, 2016]